

Robotic totally endoscopic coronary artery bypass: Program development and learning curve issues

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Background: The introduction of new procedures in heart surgery is a critical phase that includes learning curves and the risk of increased mortality or morbidity. Totally endoscopic coronary artery bypass grafting using robotic techniques represents such an innovative procedure. The aim of this report is to demonstrate the safe introduction of totally endoscopic coronary artery bypass grafting using a stepwise and modular approach.

Methods: From June 2001 until December 2002, 50 procedures were performed using the da Vinci telemanipulator system. After baseline training the following procedure modules were carried out in a stepwise manner: robotically assisted endoscopic left internal thoracic artery harvesting and completion of the procedure as conventional coronary artery bypass grafting, minimally invasive direct coronary artery bypass, or off-pump coronary artery bypass ($n = 19$), robotically assisted suturing of left internal thoracic artery to left anterior descending anastomoses during conventional coronary artery bypass grafting ($n = 15$), totally endoscopic coronary artery bypass grafting on the arrested heart using remote access perfusion and aortic endocclusion coronary bypass grafting ($n = 15$). One patient was excluded intraoperatively from a robotic procedure due to pleural adhesions.

Results: A significant learning curve was observed for left internal thoracic artery takedown time, $y(\min) = 181 - 39 \times \ln(x)$ (x = procedure number) ($P < .001$), and total operative time in totally endoscopic coronary artery bypass grafting, $y(\min) = 595 - 87 \times \ln(x)$ (x = (procedure number) ($P = .028$). The conversion rate in totally endoscopic coronary artery bypass grafting was 2/15. Intensive care unit stay correlated significantly with total operative time ($r = .427$, $P = .002$). There was no hospital mortality.

Conclusion: Totally endoscopic coronary artery bypass grafting can be safely implemented into a heart surgery program. Learning curves are steep for robotic left internal thoracic artery takedown and for performance of totally endoscopic coronary artery bypass grafting. Long operative times translate into prolonged intensive care unit stay in specific cases but not into increased mortality.

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After unsuccessful attempts to perform totally endoscopic coronary artery bypass grafting (TECAB) using conventional thoracoscopic instrumentation,¹ robotic technology has enabled heart surgeons to carry out such procedures.²⁻⁴ As with any new technique in surgery, learning curves are involved with new operations, and economic ways to minimize learning curve effects would be desirable for groups initiating robotic coronary surgery programs. It is

TABLE 1. Patient demographics

Gender	
Male	41 (82%)
Female	9 (18%)
Age	60 (43-75)
Angina	
CCSC I	1 (2%)
CCSC II	15 (30%)
CCSC III	26 (52%)
CCSC IV	8 (16%)
LVEF	62% (40-81)
COPD	2 (4%)
PVD	3 (6%)
CVD	2 (4%)
Chronic renal failure	0 (0%)
EuroSCORE	2 (0-7)

CCSC, Canadian Cardiovascular Society Classification; LVEF, left ventricular ejection fraction; COPD, chronic obstructive pulmonary disease; PVD, peripheral vascular disease; CVD, cerebral vascular disease.

most likely that several groups will start robotic coronary artery bypass grafting (CABG) in the near future, and communicating learning curve experience is critical within the cardiac surgery community. It was therefore the aim of this study to report on the development of our own program toward reproducible performance of TECAB procedures and to evaluate the major learning curves during a stepwise and modular approach to these operations. It was also an intention to give detailed information on specific problems that occurred with initial application of robotic technology.

Methods

Between June 2001 and December 2002, 50 consecutive robotically assisted coronary artery bypass grafting procedures using the da Vinci (Intuitive Surgical, Sunnyvale, Calif) telemanipulator system were carried out at our institution. Patient demographics are listed in Table 1. Informed consent from every patient and institutional ethics committee approval for performance of TECAB operations were obtained. The telemanipulation system was purchased and used as an interdisciplinary device shared with the departments of urology, general surgery, and gynecology.

Anesthesia

During intravenous anesthesia and relaxation, the patients were ventilated with oxygen and air to keep the end-tidal PCO_2 between 35 and 45 mm Hg. In cases of endoscopic left internal thoracic artery (LITA) harvesting a double lumen endotracheal tube was used. Intraoperative transesophageal echocardiography was performed in all patients; those undergoing TECAB received bilateral radial arterial pressure lines for additional monitoring of the ascending aortic balloon position. Percutaneous defibrillator patches were also used in these cases.

The following stepwise approach was taken toward performance of TECAB. It needs to be noted that the procedure modules were partly overlapping and that after successful TECAB earlier steps of the program were again carried out. The procedures

TABLE 2. Procedures performed

Intraoperative exclusion (adhesions)	1 (2%)
LITA takedown + conventional CABG	8 (16%)
LITA takedown + MIDCAB	6 (12%)
LITA takedown + OPCAB	5 (10%)
LITA takedown + robotically sutured anastomosis via sternotomy	8 (16%)
Robotically sutured anastomosis via sternotomy	7 (14%)
TECAB (arrested heart, port access)	15 (30%)
Total	50 (100%)

LITA, Left internal thoracic artery; CABG, coronary artery bypass grafting; MIDCAB, minimally invasive direct coronary artery bypass; OPCAB, off-pump coronary artery bypass.

performed during development of the program are listed in Table 2, and Table 3 shows the chronological order of the operations.

Module 1: Thoracoscopic Internal Thoracic Artery Harvesting

The patient was positioned in a 30° right lateral decubitus position. After setup of the da Vinci system a camera port was introduced into the left fifth intercostal space on the anterior axillary line under left lung collapse. CO_2 was insufflated at target pressures of 10 mm Hg. Instrument ports were then inserted through the third and seventh intercostal space on the mamillary line under thoracoscopic vision. The internal thoracic artery (ITA) was localized and the endothoracic fascia and transverse thoracic muscle were removed from the ITA pedicle to adequately visualize the vessel. Using electrocautery at 20 W and endoscopic clips for division of pedicle side branches, the ITA was harvested from the first onto the fifth intercostal space. Heparin was given, and after endoscopic placement of a temporarily occluding bulldog clamp, preparation of the distal graft portion as well as free flow check were carried out.

Module 2: Pericardial Lipectomy and Pericardiotomy, Target Vessel Identification

For this module the robotic system was again applied and the same ports as for LITA takedown were used. The pericardial fat pad was grasped with long-tip endoscopic forceps and removed from the pericardium using electrocautery. After incision of the pericardium at the sternal border and further lateral incision of the visible pericardium, the left anterior descending artery (LAD) was identified and marked with a clip onto the adjacent epicardium. Care was taken to see the LAD running around the apex of the heart to avoid confusion with diagonal branches.

Module 3: Suturing of the LITA to Target Vessel Anastomosis through Sternotomy Using the da Vinci System

In multivessel CABG anastomoses to the right coronary artery or circumflex artery systems were performed on cardiopulmonary bypass and on the arrested heart using conventional open heart microinstruments. The LITA to target vessel anastomosis was carried out last using the da Vinci system. The epicardial fat was incised with an endoscopic beaver blade knife. Thereafter the target vessel was exposed and incised with a lancet endoscopic

TABLE 3. Chronological order of procedure modules

Patient number	ITA takedown	Pericardial lipectomy	Pericardiotomy	Anastomotic suturing	TECAB
1	+				
2	+				
3	+				
4	+				
5	+				
6	+				
7	+				
8	+				
9	+				
10	+				
11	+				
12	+	+	+	+	+
13	+				
14	+				
15	+	+	+	+	+
16	+	+	+		conv
17	+				
18	+				
19	+				
20	+			+	
21	+			+	
22	+			+	
23	+				
24	+			+	
25	+			+	
26				+	
27				+	
28	+	+	+		
29	+			+	
30	+	+	+	+	+
31	+	+	+	+	+
32	+				conv
33	+			+	
34	+	+	+	+	+
35	+	+	+	+	+
36	+	+	+	+	+
37	+	+	+	+	+
38	excl adh				
39				+	
40				+	
41	+			+	
42					+
43	+				
44	+	+	+	+	+
45	+	+	+	+	+
46				+	
47	+	+	+	+	+
48	+	+	+	+	+
49	+	+	+	+	+
50				+	

ITA, Internal thoracic artery; TECAB, totally endoscopic coronary artery bypass grafting; *excl adh*, intraoperative exclusion for severe intrathoracic adhesions; *conv*, conversion (TECAB planned).

knife under running cardioplegia. The LITA was then sutured robotically to the target vessel using a 7-0 double-armed Pronova (Johnson & Johnson [Somerville, NJ] PN 8713) running suture.

TABLE 4. Operative times

LITA take down time (min)	63 (35-180)
LITA to target vessel robotical anastomotic time (min)	33 (22-50)
Operative time (all procedures) including quality control (min)	360 (247-690)
Operative time TECAB including quality control and on table revisions	420 (270-690)

LITA, Left internal thoracic artery; TECAB, totally endoscopic coronary artery bypass grafting.

Module 4: Arrested Heart Totally Endoscopic Single-Vessel Coronary Artery Bypass Grafting

ITA harvesting, pericardial lipectomy, and pericardiotomy were carried out as described above. In parallel to these steps the femoral artery and femoral vein were exposed in the left groin. After systemic heparinization the right atrium was cannulated for cardiopulmonary bypass using a 25F or 27F Medtronic venous return cannula (96370 Medtronic, Minneapolis, Minn). A 21F Remote Access Perfusion (ESTECH, Danville, Cal) cardiopulmonary bypass system or 21F Endoreturn (Heartport, CardioVations Somerville, NY) arterial cannulae were inserted, cardiopulmonary bypass was started, and the ascending aortic occlusion balloon was inflated for induction of cardioplegia. The patients were then cooled to 25°C rectal temperature to allow reduced cardiopulmonary bypass flow in cases of target vessel back-bleeding. The incision of the target vessel and suturing of the anastomosis were carried out as described above.

Intraoperative patency of robotically sutured bypass grafts were assessed by angiography carried out through femoral arterial access. The examinations were performed by a cardiologist in cooperation with the heart surgeon. Grafts were regarded as nonpatent if narrowing greater than 50% was present.

During the time frame of the current series 12 atrial septal defect (ASD) repairs and 4 mitral valve repairs were carried out using the ESTECH or Heartport, CardioVations cardiopulmonary bypass system to guarantee regular application of these devices between TECAB procedures.

Statistics

Statistical calculations were performed on SPSS 11.0 statistical software package (SPSS Inc, Chicago, Ill). Continuous variables are given as median and range, and categorical variables are given as absolute values and percentages. For calculation of learning curves regression models with logarithmic curve fit were applied. Correlations were calculated using nonparametric tests and Spearman rho correlation coefficient.

Results

There were no major intraoperative technical failures of the da Vinci telemanipulator system. Operative times are listed in Table 4. Learning curves for thoracoscopic ITA harvesting, for complete TECAB, and for LITA to target vessel suturing are shown in Figure 1, Figure 2, and Figure 3.

We experienced 2 conversions (2/15 = 13%) to standard on-pump CABG in TECAB. One conversion was necessary

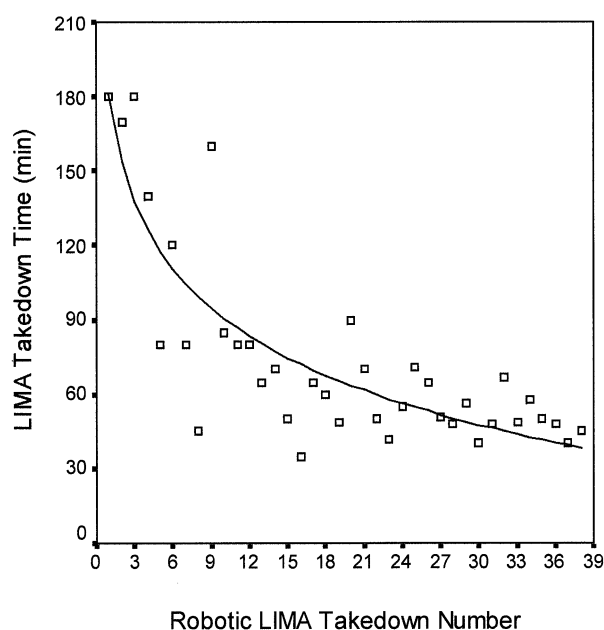


Figure 1. During the learning curve in 38 patients the robotic LITA harvesting time decreased from 180 minutes at the beginning of the series to approximately 50 minutes in the last cases. The learning curve was significant ($P < .001$) and followed the function: $y = 181 - 39 \times \ln(x)$, where y = LITA takedown time and x = consecutive LITA takedown number.

for an intramural hematoma in the ITA, which resulted in cessation of flow; a second conversion was necessary during cardioplegia because of massive backflow from the target vessel.

Twenty-four grafts that were sutured robotically were investigated by intraoperative angiography. In 2 patients extravasation of contrast agent at the anastomosis was noted. A manual on table repair via minithoracotomy was carried out in the first case. In another case in addition to bleeding from the anastomosis significant narrowing of the LITA 2 cm proximal to the anastomosis was detected. The graft was immediately revised through sternotomy with perfect patency on intraoperative repeat angiography. In 1 case of robotic LITA to LAD suturing a manual repair stitch after bleeding from the anastomosis led to significant narrowing of the anastomosis. This anastomosis was completely revised, again with a perfect result on intraoperative repeat angiography. The other 21 grafts showed a normal graft course, an open anastomosis, and unimpaired proximal as well as distal run off. Finally all 24 patients left the operating room with a patent and functioning LITA graft.

As listed in Table 5, our rate of perioperative major adverse cardiac and cerebral events was low. Prolongation of ventilation time over more than 24 hours was necessary in 3 of 50 patients (6%) for the following reasons: patient 1, postoperative bleeding (disturbed coagulation) and hemo-

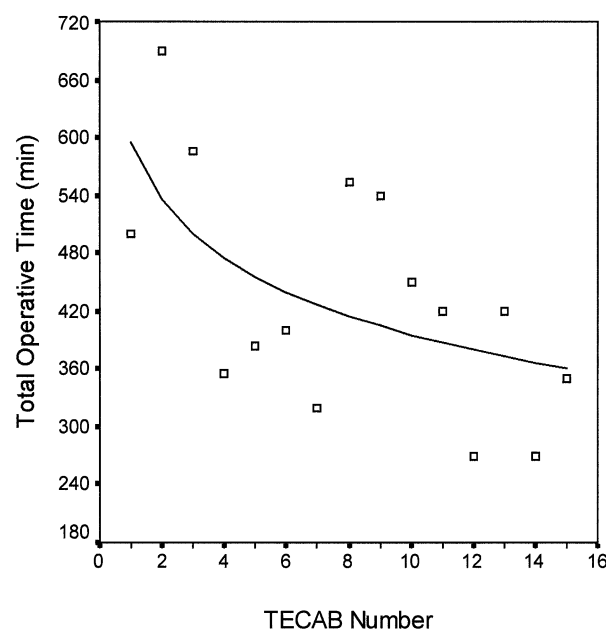


Figure 2. During the learning curve in 15 patients operative times in TECAB decreased from approximately 9 hours to approximately 6 hours. Intraoperative angiography for quality control and revisions on table are included. The learning curve was significant ($P = .028$) and followed the function: $y = 595 - 87 \times \ln(x)$, where y = total operative time in TECAB and x = consecutive TECAB number.

dynamic compromise plus multiorgan dysfunction after planned conversion to standard on-pump CABG; patient 2, hemodynamic compromise plus multiorgan dysfunction after conversion from TECAB to standard CABG because of massive retrograde flow from the target vessel; patient 3, aggressive postoperative neuropsychological behavior most likely due to concomitant respiratory infection after uncomplicated robotic LITA to LAD suturing via sternotomy. Two of these patients required hemofiltration for treatment of renal failure.

Thirty-day mortality was 0 of 50 (0%). As shown in Figure 4 there was a correlation between total operative time and intensive care unit stay. The cosmetic result after TECAB is shown in Figure 5.

Discussion

In 1996 Stevens and coworkers¹ reported the first attempts at performing TECAB in animal models and in a few clinical pilot cases. It was soon noted that these procedures could not be carried out using the thoracoscopic instrumentation that was available at that time. During the following years robotic devices were constructed that allowed the first TECAB procedure to be carried out by Loulmet and colleagues² in 1998. Subsequent clinical series were performed and reported by active groups in Frankfurt,⁴ Dresden,⁵ and Leipzig.⁶ Encouraged by the performance of these surgeons,

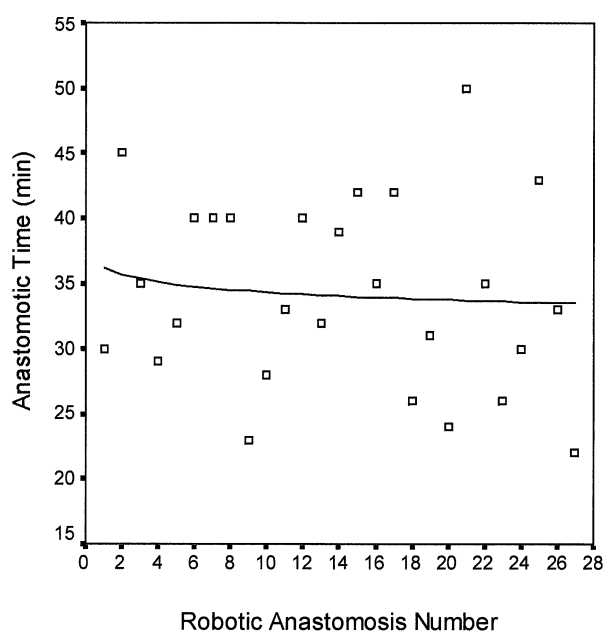


Figure 3. The robotic LITA to target vessel anastomotic time showed no significant learning curve and a median of 33 minutes. No significant learning curve was present.

TABLE 5. Perioperative outcomes

	All procedures	TECAB
Conversion to sternotomy		2/15 (13%)
Surgical revision for bleeding	3/50 (6%)	2/15 (13%)
Myocardial infarction	2/50 (4%)	1/15 (7%)
IABP	2/50 (4%)	0/15 (0%)
Ventilation time (h)	13 (0-278)	10 (1-278)
Pneumonia	2/50 (4%)	1/15 (7%)
Hemofiltration	2/50 (4%)	0/15 (0%)
TIA	0/50 (0%)	0/15 (0%)
Stroke	0/50 (0%)	0/15 (0%)
Deep wound infection	1/50 (2%)	0/15 (0%)
ICU stay (h)	24 (12-282)	23 (16-282)
Hospital stay (d)	8 (5-25)	7 (5-15)
30-day mortality	0/50 (0%)	0/15 (0%)

TECAB, Totally endoscopic coronary artery bypass grafting; IABP, intra-aortic balloon pump; TIA, transient ischemic attack; ICU, intensive care unit. Results in TECAB include converted patients to maintain the intent-to-treat basis.

our department decided to start a robotic coronary artery surgery program in 2001.

Patient Selection

As can be seen from the demographic data we chose low-risk patients with few comorbidities for our initial robotic

CABG series. The main argument for this approach was to keep reserves should intraoperative problems occur. Our 0% mortality in the whole series speaks for this careful patient selection mode.

Operative Times and Learning Curves

Our learning curves are comparable with those described by the groups mentioned above. Kappert and coworkers⁵ noted a reduction of ITA takedown times from approximately 90 minutes at the beginning of the robotic CABG program to approximately 50 minutes after 35 patients. Falk and colleagues⁶ described a similar drop in ITA takedown times from approximately 120 minutes to approximately 50 minutes after 35 patients. Using the Zeus (Computer Motion Inc, Goleta, Calif) telemanipulator system, Boehm and colleagues⁷ have also experienced endoscopic ITA takedown times that are comparable with our results. The literature provides robotic LITA to LAD anastomotic times in the range between 16 and 32 minutes^{2,5,7-10} using both the da Vinci and the Zeus systems. Our anastomotic times are only slightly longer than those reported. We think that the most probable reason for a more pronounced learning curve in ITA takedown times as compared with anastomotic times is that the main primary learning steps such as clinical adaptation of the system were overcome during this period. In addition, slaughterhouse pig hearts were used for training with robotic anastomotic suturing, and major parts of the corresponding learning curve had already been overcome.

Total operative time in TECAB showed a dramatic learning curve and we think that this represents a sum of learning curves and a potentiating effect if the learning curves of the different procedure modules are overcome. With a procedure time of 270 minutes, in 2 of our last TECAB patients we reached an acceptable time range.¹⁰ It needs to be mentioned that long operative times of approximately 330 minutes have also been experienced by others^{6,7} during TECAB development. In addition times for quality control by intraoperative angiography and revision times for bleeding repairs in the immediate postoperative period are included in our calculations.

Modular Approach

The complexity of arrested heart TECAB would most likely lead to an extraordinary long operative time if all surgical steps were carried out without prior splitting of the procedure into learning curve modules. We decided to divide the procedure into the following modules: ITA takedown, performance of intermediate steps like pericardial lipectomy and opening of the pericardium, anastomotic suturing, and clinical application of remote access perfusion and aortic endocclusion in operations other than TECAB. We insisted on regular performance of these modules interposed between totally endoscopic procedures, which are rare due to current catheter-based interventional approaches to single-

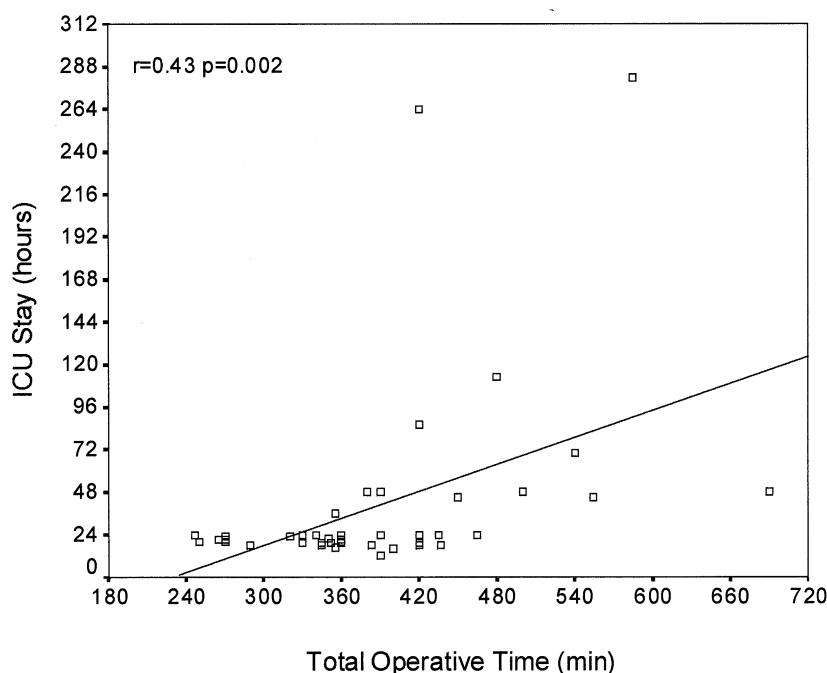


Figure 4. Postoperative intensive care unit (ICU) stay correlates with total operative time.

vessel coronary artery disease. Falk and coworkers⁶ followed a similar clinical training plan and also succeeded in safely introducing arrested heart TECAB.

Clinical Outcome

We consider the 0% 30-day mortality achieved in our series as highly satisfying. Other authors have also noted very low mortality rates during introduction of robotically assisted CABG programs.^{5,7,8} We would like to emphasize that despite the learning curves involved, the observed mortality did not reach EuroSCORE predictions. Furthermore, the low rate of adverse cardiac events is satisfying especially in light of the fact that the LITA to target vessel anastomoses in our series were performed with the da Vinci system with acceptable primary anastomotic patency. The use of intra-operative angiography for quality control allowed detection of anastomotic bleeding or narrowing in 3 patients. Successful immediate graft revision was carried out in all these cases, and adequate graft patency as well as function were achieved at the end of the procedure. Major problems with robotically sutured LITA grafts were not encountered by other groups either, and the early patency rates of these grafts seem to be well above 90%.^{6,8}

Our conversion rate in TECAB is comparable to those described in the literature. The Frankfurt group¹⁰ has stressed the fact that conversions primarily occur during the learning phase and that the conversion rate can be reduced thereafter. In both patients who needed conversion we noted problems that have also been described by others.^{6,9}

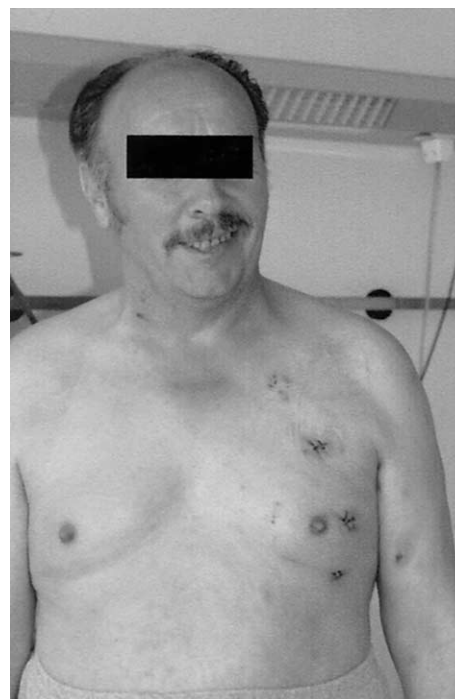


Figure 5. Minimized surgical trauma in TECAB. The bypass graft was placed through 3 ports on the left thoracic wall.

Of the patients who required prolonged ventilation and intensive care unit stay, only 1 exhibited a problem that could be directly related to the robotic procedure. In this TECAB patient conversion to standard CABG was neces-

sary after cardioplegia through the percutaneous cardiopulmonary bypass system. Massive backflow from the target vessel was noted, which did not allow safe suturing of the anastomosis. Sternotomy under cardioplegia and technical problems during open manual suturing of the anastomosis prolonged aortic crossclamp time as well as cardiopulmonary bypass time. This may have been the major reason for development of postoperative multiorgan dysfunction in this 70-year-old patient. Based on this case we decided to offer the completely endoscopic procedure to patients of younger age. By comparison other authors have chosen young patients with few comorbidities for their initial series in robotically assisted CABG as well.^{2,5,6,10}

Conclusion

We conclude that robotically assisted TECAB can be introduced safely into a heart surgery program. The learning curve is steep for ITA harvesting and for performance of arrested heart TECAB but is less pronounced for other parts of the totally endoscopic bypass grafting procedure. Learning curve problems as expressed by extensive operative times may translate into prolonged intensive care unit time. The overall outcome, however, despite performance of operations during a learning phase, can be better than expected by risk score predictions. A stepwise and modular approach interposing clinical training modules between TECAB cases therefore seems worthwhile.

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